UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ANDREW BARKER and SARAH BARKER, individually and as natural parents and guardians of N.B., a minor,	)	
Plaintiffs,	)	Case No. 1:11-CV-0938 TWP-DKL
vs.	)	
CAREFUSION 303, INC., f/k/a ALARIS MEDICAL SYSTEMS, INC. AND CARDINAL HEALTH 303, INC., and CAREFUSION CORPORATION,	)	
Defendants.	)	

SECOND AMENDED COMPLAINT FOR DAMAGES AND REQUEST FOR JURY TRIAL

PARTIES

Plaintiffs, Andrew and Sarah Barker, individually and as natural parents and guardians of N.B., a minor, for Damages against Defendant CareFusion 303, Inc., f/k/a Alaris Medical Systems, Inc. and Cardinal Health 303, Inc., and CareFusion Corporation states:

JURISDICTION AND VENUE

1. The Plaintiffs are Andrew and Sarah Barker who are husband and wife and residents of Marion County, State of Indiana.

2. Andrew and Sarah Barker are the natural parents and guardians of N.B., a minor child.

3. CareFusion 303, Inc., ("CareFusion 303"), formerly known as Alaris Medical Systems, Inc. and Cardinal Health 303, Inc., ("Cardinal 303"), (hereinafter collectively referred to as "Defendants"), were foreign corporations registered to do business in the State of Indiana.

4. CareFusion Corporation (hereinafter collectively referred to as "Defendants") is a publicly-held foreign company organized under the laws of the State of Delaware whose principal place of business is located in the State of California, and which wholly owns defendant CareFusion 303.

5. This Court has jurisdiction pursuant to 28 U.S.C.A. § 1332(a) as the parties are diverse and the amount in controversy exceeds $75,000.

6. Venue in the suit lies in the Southern District of Indiana pursuant to 28 U.S.C. § 1391(a) because a substantial part of the events giving rise to the claims alleged herein occurred within the Southern District of Indiana.

FACTUAL ALLEGATIONS

I. N.B. was Injured While Receiving Medical Fluids Delivered by the Alaris PC Unit

7. At all times relevant, the Defendants were in the business of designing, manufacturing, constructing, assembling, inspecting, and selling medical equipment and the component parts thereof, including the Alaris PC Unit Model 8000, the Alaris Pump Module 8100 and the Alaris Syringe Module 8110 (hereinafter collectively referred to as the "System").

8. At all times relevant, the Defendants were in the business of designing, manufacturing, constructing, assembling, inspecting, and selling component parts of the System, including the clamps, springs, coils, "fingers," syringes, key pads and administration sets used with the System to administer intravenous medical fluids and medications.

9. On November 11, 2009, N.B. was a patient at Sisters of St. Francis Health Services, Inc. d/b/a St. Francis Hospital and Health Centers (hereinafter "St. Francis"), in Indianapolis, Indiana.

10. On November 11, 2009, N.B. was receiving medical fluids, including total parenteral nutrition or, TPN, and oral gastric feedings, by way of the system. The medical fluid was being administered via an Alaris PC Unit Model 8000 believed to be serial number 9881887; an Alaris Pump Module 8100, believed to be serial number 9882700; and an Alaris Syringe Module 8110 believed to be serial number 9922641. Also attached to the PC Unit was a second 8110 Syringe Module, believed to be serial number 9922599 and a second 8100 pump module believed to be serial number 12380158. The activity of the System was recorded on an "Event Log."

11. According to N.B.'s medical records from St. Francis, on November 11, 2009, at approximately 11:30 am, an order was received by the nursing staff to discontinue N.B.'s TPN. The umbilical vein catheter, through which the TPN was delivered, was to be removed.

12. The Event Log indicates that at 1:15:30 pm the System was powered off, that the shut down was complete, and that the pumps in the System were idle. (True and Accurate Copies of Portions of the Event Log from 7:13:56 am to 3:34:25 pm. are attached as *Exhibit A*.)

13. While the Event Log indicates that the pumps in the System remained idle and the System was powered off, between 1:15 pm and 1:40 pm, the System malfunctioned causing the administration of TPN to N.B. in an excessive amount at a very rapid and unsafe rate, which caused N.B. to become unresponsive and suffer a respiratory/cardiac arrest.

14. Shortly before 1:40 pm on November 11, 2010, Sarah and Andrew Barker arrived at N.B.'s bedside for visitation and witnessed his arrest and the resuscitation efforts that followed.

15. As a result of the inadvertent rapid infusion of TPN, N.B. suffered brain damage. He has incurred medical expenses, loss of quality of life, a reduction of income earning ability,

and will continue to incur the same. N.B. suffered and continues to suffer extreme emotional and physical pain and is permanently disabled. However, due to the fact that N.B. is now 2 years and 2 months old, the Plaintiffs' and N.B.'s health care providers are uncertain of the total extent and effects of the damages and injuries N.B. has incurred and such will not be known until N.B. reaches at least 5 or 6 years of age.

16. As a direct and proximate result of the negligence and carelessness of the Defendants, N.B., Andrew W. Barker and Sarah R. Barker have been damaged and have suffered great pain and mental anguish.

II. Defendant Had Knowledge of the Inadvertent Over Infusion of Fluids Occurring with the System at Issue

17. On October 29, 2007, the Defendants issued a Class 1 recall of its Alaris Model 8100 modules shipped before September 27, 2007.

18. According to the recall either during the manufacturing or servicing of the mechanism assembly, the occluder springs were misassembled (overlapping [nested], missing, bent or broken). If a spring is misassembled, there is a potential for inaccurate flow rate which may lead to a patient's harm due to over infusion. According to the FDA, over infusion could be difficult to detect because the misassembled springs could work intermittently and there was no warning or notification of over infusion.

19. Customers were provided with a list of pumps thought to contain the misassembled occluder springs.

20. On November 5, 2007, Cardinal 303 issued a recall notice that included "Service Bulletin 528" describing an interim test to verify the presence of the System's occluder springs. The initial test did not accurately verify the presence of, or problems with, the occluder springs

within the System, and the Defendants issued a new service bulletin "528A" on December 5, 2007.

21. Systems shipped after September 27, 2007, underwent a "new" inspection process meant to confirm that the occluder springs had been properly assembled.

22. From January 8 to February 1, 2008, the FDA inspected the Defendants operation and found the Systems (a) adulterated within the meaning of Act, 21 US.C. § 351(h) and misbranded within the meaning of the Act, 21 U.S. C. § 352(t)(2), for failure to submit reports of correction and removals of medical device reports. The FDA further determined that Defendants violated Act 21, U.S.C. § 331 (a) and § 351(h) by introducing or delivering into interstate commerce, their infusion pumps that were adulterated and misbranded.

23. In October 2008, the 8100 pump serial number 9882700 used on N.B. was sent to the Defendants and underwent an LVP x-ray inspection. The pump was then returned to St. Francis for continued use.

24. On February 18, 2009, Defendants entered into an Amended Consent Decree with the FDA regarding its System. By the terms of the Decree, Cardinal 303 was required to retain an expert to complete a comprehensive inspection of the infusion pump facilities and certify in writing whether Cardinal 303 had corrected all deviations set forth in the FDA's Inspectional Observations. The expert was also required to certify that the Defendant conformed with CGMP, 21 U.S.C. §§ 351 (h) and 352 (t)(2), 21 C.F.R. Parts, 803,806, and 820 and the Amended Decree. More specifically, the Decree required identification of steps taken by Cardinal 303 to identify the root causes for the (a) bent, broken, missing or nested occluder spring problems; (b) U3, U6, U9 and U19 chip socket problems; (c) IUI connector problems; (d) broken or cracked door problems and (e) all other identified deficiencies in the System.

25. On June 12, 2009, the Defendants issued another recall of the System. According to the recall, the occluder fingers of the pumping mechanism lose their resilience due to certain types of fluids solidifying them (fingers). This would result in loss of the occluder finger motion and over infusion of medication.

III. Defendants were Aware of Numerous Incidents of Unexpected, Unintended Sudden and Rapid Over Infusion Occurring with the System

26. Between 2006 and 2009 when the injury to N.B. occurred, a significant number of adverse events regarding the over infusion of fluids through use of the System, had been reported to the FDA.

27. Before 2009, a number of unintended, sudden and rapid over infusions had occurred with the System after the System had been powered off.

28. Despite its knowledge that the System was defective and unreasonably dangerous, the Defendants manufactured and sold the System at issue in wanton disregard for the safety, health, and welfare of N.B. and others.

IV. The System is Defective in Manufacture and/or Design, Rendering it Unreasonably Dangerous for Reasonable Use by Intended Consumers.

29. The System manufactured and/or designed and distributed by the Defendants was defective, making it unreasonably dangerous to consumers and users.

30. N.B. is a user who was in the class of persons that the Defendants should have reasonably foreseen as being subject to the harm caused by the defective System.

31. The defect in the System is attributable to the Defendants.

32. The System manufactured and distributed by Defendants was defective in manufacture and/or design and was unreasonably dangerous in that it contained bent, broken, missing or nested occluder springs problems causing over infusion of medical fluids.

33. The System manufactured and distributed by Defendants was defective in manufacture and/or design and was unreasonably dangerous in that it had U3, U6, U9 and U19 chip socket problems causing over infusion of medical fluids.

34. The System manufactured and distributed by Defendants was defective in manufacture and/or design and was unreasonably dangerous in that it had IUI connector problems causing over infusion of medical fluids.

35. The System manufactured and distributed by Defendants was defective in manufacture and/or designs and was unreasonably dangerous in that it had broken or cracked door problems causing over infusion of medical fluids.

36. The System manufactured and distributed by Defendants was defective in manufacture and/or design and was unreasonably dangerous in that it may also have problems or issues with key bounce, tubing failure, defects in the paten, tubing well and fitment recess, causing misloading of tubing, and/or fluid ingress causing loss of motion of the occluder fingers. All the above defects cause over infusion of fluids.

37. Defendants negligently selected, assembled, manufactured and distributed the System.

38. Defendants knew or had reason to know that, as manufactured and assembled, the System was unreasonably dangerous because of defects in manufacture and/or design in that the Defendants were aware of numerous reports, prior to November 2009, that unintended over infusion could occur after the System was powered off.

39. The defective manufacture of the System proximately caused the Plaintiffs injuries.

V. The System is Defective in Warnings and Instructions Rendering It Unreasonably Dangerous for Reasonable Expected Use by Intended Consumers.

40. Defendants failed to provide reasonable instructions and warnings of dangers about the System it manufactured in light of the risks associated with over infusion of fluid after powering off the System thereby rendering the product defective and unreasonably dangerous.

41. Defendants failed to exercise reasonable care under the circumstances in providing warnings and instructions for use of its System, and the potential for over infusions after powering off the System.

42. The danger of over infusion after powering off the System is not one a reasonable consumer would expect to find or encounter.

43. The increased danger of over infusion of fluids after powering off the System is not one a reasonable consumer would know.

44. Inadvertent over infusion of fluids after powering off the System is not contemplated by reasonable persons among those considered expected users or consumers of the System.

45. Inadvertent over infusion after powering off the System is a condition that is unreasonably dangerous to the expected user of the System when using the System in a reasonably expectable manner.

Scope

46. Defendants failed to provide reasonable instructions or warning with the System rendering the product defective and unreasonably dangerous in that it did not include a warning on the System stating that over infusion could occur from normal or expected use, such as when the System was powered off.

47. Defendants failed to provide reasonable instructions or warnings with the System rendering the product defective and unreasonably dangerous in that it failed to adequately explain the nature of the risks associated with bent, broken, missing or nested occluder spring problems.

48. Defendants failed to provide reasonable instructions or warnings with the System rendering the product defective and unreasonably dangerous in that it failed to adequately explain the nature of the risks associated with U3, U6, U9 and U19 chip socket problems.

49. Defendants failed to provide reasonable instructions or warnings with the System rendering the product defective and unreasonably dangerous in that it failed to adequately explain the nature of the risks associated with the IUI connector problems.

50. Defendants failed to provide reasonable instructions or warnings with the System rendering the product defective and unreasonably dangerous in that it failed to adequately explain the nature of the risks associated with the broken or cracked door problems.

51. Defendants failed to provide reasonable instructions or warnings with the System rendering the product defective and unreasonably dangerous in that it failed to adequately explain the nature of the risks associated with key bounce, tubing failure, defects in the paten, tubing well and fitment recess, causing misloading of tubing, and/or fluid ingress causing loss of motion of the occluder fingers.

Conspicuousness

52. Defendants failed to provide reasonable instructions or warnings with the System rendering the product defective and unreasonably dangerous in that the safety instructions concerning an unintended over infusion are not reasonably calculated to catch the attention of a reasonably prudent user under the circumstances.

53. Defendants failed to provide reasonable instructions or warnings with the System rendering the product defective and unreasonably dangerous in that the safety instructions regarding over infusion are not printed in sufficient size and color to draw a reasonable user's attention.

54. All of the warnings in the user manual are in black ink on white paper, there is no color indicating danger or warnings.

Intensity

55. Defendants failed to provide reasonable instructions or warnings with the System rendering the product defective and unreasonably dangerous in that the warnings regarding inadvertent over infusion are not of an intensity justified by the magnitude of the risk of over infusion.

56. Defendants' warnings and instructions regarding the importance of reading and following the user manual instructions do not explain the possibility of serious injury as the reason why the user should read and follow the manual's instructions.

57. If Defendants had provided proper warnings, the warnings would have been heeded, the users of the System would have been alerted to the danger of over infusion while the System was powered off, and N.B. would not have been injured.

58. As a result of Defendants' failure to provide proper warnings, the Plaintiffs suffered the injuries described herein.

59. The Plaintiffs' injuries were caused by a defect which the Plaintiffs were not aware of nor reasonably could have been aware.

VI. The Arrest of N.B. Caused by the Defect in the System Was Witnessed by Andrew Barker and Sarah Barker.

60. The November 11, 2009 incident that caused injury to N.B. was witnessed by his parents, Andrew Barker and Sarah Barker.

61. As a direct and proximate result, Andrew Barker and Sarah Barker have suffered and continue to suffer from the emotional distress of witnessing the incident together with the immediate aftermath.

62. As a direct and proximate result of the negligence and carelessness of the Defendants, Andrew and Sarah Barker have been damaged and have suffered great pain and mental anguish.

WHEREFORE, Plaintiffs, by counsel, respectfully request a judgment against the Defendants in an amount which will compensate them for their losses, for the costs of this action, trial by jury, and for all other just and proper relief in the premises.

REQUEST FOR JURY TRIAL

Plaintiffs respectfully request trial by jury.

Respectfully submitted,

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 24th day of February, 2012, a copy of the foregoing was electronically filed with the Court using the CM/ECF system which sent notification of such filing to the following:

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